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EXAMINER
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CROW, ROBERT THOMAS

ART UNIT	PAPER NUMBER
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1634

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/526,402	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Robert T. Crow	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,9-27,29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 9-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,26,27,29 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 12 May 2009 in which claims 1 and 4 were amended, claims 5-8 and 30 were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The objections to the claims listed in the previous Office Action are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-2, 4, 26-27, 29, and 31 are under prosecution.

2. This action is non-final because of the rejections under 35 U.S.C. 112, second paragraph presented below.

### ***Bib Data Sheet***

3. The Bib Data Sheet signed 21 August 2007 was missing the inventor Jae Young Jang. A new Bib Data Sheet, including all inventors listed on the Declaration filed 7 November 2005 and in the Application Data Sheet filed 2 March 2005, is signed with this Office Action. The examiner apologizes for any confusion.

***Claim Interpretation***

4. Claim 1 has been amended to recite “tetramethyl orthosilicate (~~TMOS~~), tetraethyl orthosilicate (TEOS), methyltrimethoxysilane (MTMS), ethyltriethoxysilane (ETEOS), trimethoxysilane (TMS), and 3-aminopropyltrimethoxysilicate (APT MOS)” in lines 9-12 and also recites “polyglycerylsilicate (PGS), 3-glycidoxypropyltrimethoxysilane (GPT MOS), (N-triethoxysilylpropyl)-O-polyethylene oxide urethane (PEOU), glycerol, and polyethylene glycol (PEG)” in lines 13-15. Support for this amendment is found on page 7 of the instant specification. A review of the specification finds no further definition of the acronyms present in the claim. In addition, page 7 of the claim specifically defines polyethylene glycol and “PEG” to have a molecular weight “in the range of 400 to 10,000.” Therefore, the acronyms are limited to the compounds specifically described on page 7 of the specification, and the recitations of polyethylene glycol and “PEG” are limited to PEG compounds having a molecular weight in the range of 400 to 10,000.

***Claim Rejections - 35 USC § 112, Second Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2, 4, 26-27, 29, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1, upon which claims 2, 4, 26-27, 29, and 31 depends recites the broad recitation "poly(methyl vinyl ether-maleic anhydride) having a molecular weight of 200,000 or more" in lines 21-22, and the claim also recites "poly(methyl vinyl ether-maleic anhydride) having a molecular weight of 1,000,000 or more" in line 22-23 which is the narrower statement of the range/limitation.

7. The following rejections are new rejections necessitated by the amendments.

***Claim Rejections - 35 USC § 112, First Paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 1-2, 4, 26-27, 29, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a new matter rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1, upon which claims 2, 4, 26-27, 29, and 31 depend, recites gels spots that “have a spherical shape of three-dimensional structure” in line 3. While Example 3 of the instant specification discusses spots having “most excellent three dimensional structure,” a review of the specification yields no teaching of spots having “spherical” shape or structure. Therefore, the recitation of spots that have a “spherical” shape constitutes new matter.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

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commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-2 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Avnir et al (U.S. Patent No. 5,292,801, issued 8 March 1994) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

Regarding claim 1, Kim et al teach a biochip in the form of Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph); and the polyvinyl acetate coating has a molecular weight of 130,000 (page 332, "Materials" section) and is dissolved in methylene chloride (page 33, column 1). The gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1). Because the biomaterials are entrapped within the gel, there is not covalent bond to the gel. The gel spots are formed by the gelation of a sol mixture on the substrate (page 333, columns 1-2). Kim et al also

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teach the gel spots are integrated in an amount of up to 1000 spots/cm<sup>2</sup>; namely, Figure 4 shows 5 spots of gel in an area approximately 1000 microns (0.1 cm) by about 700 microns (0.07 cm), based on the 100 micron bar in the Figure. The spot density is therefore  $(5 \text{ spots}) / (0.1 \text{ cm}) \times (0.07 \text{ cm}) = \text{approximately } 714 \text{ spots/cm}^2$ .

Kim et al do not teach the gels spots are glassy gels spots.

However, Avnir et al teach a biochip in the form of a support having spots (column 5, lines 55-60), wherein the spots are glassy sol-gel spots having biomaterials doped therein (Abstract). The biomaterials are trapped in the glassy sol gel without covalent modification (Abstract and column 4, lines 60-67); thus, there is no covalent bond and the biomaterials have a free orientation. The gels spots also comprise the silicate tetramethoxysilane (TMOS) and an additive in the form of PEG having a molecular weight of 400 (column 7, lines 35-55). Avnir et al also teach the gel spots have the advantage of being useful in quantitative analysis (column 1, lines 10-30). Thus, Avnir et al teaches the known technique of providing glassy gels spots.

While neither Kim et al nor Avnir et al explicitly teach the spots are spherical, Avnir et al do teach in lines 20-30 of column 3 that three dimensional shapes (e.g., rods, discs, cubes), and that the glassy gel spots are “in any shape.” The courts have found that changes in shape are obvious (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)). Thus, spherical three dimensional shape of the spots of the instant claim is an obvious variant of the three dimensional spots Kim et al in view of Avnir et al. See MPEP 2144.04 [R-6] IV B.



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It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip comprising the gel spots as taught by Kim et al so that the gel spots are the three dimensional glassy gel spots made from TMOS and PEG as taught by Avnir et al to arrive at the instantly claimed biochip with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip comprising spots having the added advantage of being useful in quantitative analysis as explicitly taught by Avnir et al (column 1, lines 10-30). In addition, it would have been obvious to the ordinary artisan that the known technique of using the glassy three dimensional gel spots of Avnir et al could have been applied to the biochip of Kim et al with predictable results because the known technique of using the glassy three dimensional gel spots of Avnir et al predictably results in spots useful for analyte binding reactions.

While Avnir et al teach the glassy spots are supported on an optical support (column 5, lines 55-60), neither Kim et al nor Avnir et al teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by

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Kim et al in view of Avnir et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al in view of Avnir et al with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

Regarding claim 2, the biochip of claim 1 is discussed above. Kim et al teach the chip is used as a protein chip; namely proteins are entrapped in the chip (page 333, column 1). Avnir et al also teach the biochip is used as a protein chip (i.e., has antibodies immobilized thereon; column 10, lines 10-50). Thus, modification of the biochip of Kim et al in view of Simon et al with the teachings of Avnir et al results in a biochip used as a protein chip.

In addition, it is noted that the courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, “[A]pparatus claims cover what a device *is*, not what a device

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does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because the prior art teaches the structural elements of the claim, the claim 2 is obvious over the prior art. See MPEP § 2114.

Regarding claims 26-27, the biochip of claim 1 is discussed above. Kim et al teach the biochip of claim 1, wherein the biomaterials are IgG (page 333, column 1), which are antigens to anti-human polyvalent IgG (i.e., claim 27) and are proteins (i.e., claim 28). In addition, Avnir et al also teach the biochip has antigens immobilized thereon; namely, anti-IL-2r, which is a protein that is an antigen to IL-2R, is immobilized in the spots (column 10, lines 10-50). Thus, modification of the biochip of Kim et al in view of Simon et al with the teachings of Avnir et al results in a biochip having antigenic proteins immobilized therein.

It is noted that the broadly claimed “antigens or antibodies for infections disease diagnosis” of claim 27 does not necessarily require the antigens to be “for infections disease diagnosis” due to the placement of the word “or” in the recitation.

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Avnir et al (U.S. Patent No. 5,292,801, issued 8 March 1994) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) as applied to claim 1 above, and further in view of Malhorta (U.S. Patent No. 5,624,743, issued 29 April 1997).

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Regarding claim 4, the biochip of claim 1 is discussed above in Section 12.

While Kim et al teach the polyvinyl acetate solution is in methylene chloride (page 333, first paragraph), neither Kim et al, Avnir et al, nor Simon et al teach the solvent is 5-20% by weight.

However, Malhorta teaches polyvinyl acetate solutions in about 10 to about 30 percent by weight (column 7, lines 40-60), which includes the claimed value of 20% by weight. Thus, Malhorta teaches the known technique of using a polyvinyl acetate solution having methylene chloride in 20% by weight.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate having a coating solution of polyvinyl acetate in methylene chloride as taught by Kim et al in view of Avnir et al and Simon et al so that the coating solution is a polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta to arrive at the instantly claimed invention with a reasonable expectation of success. It would have been obvious to the ordinary artisan that the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta could have been used as the coating solution in the chip substrate of Kim et al in view of Avnir et al and Simon et al with predictable results because the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta predictably results in a useful coating solution concentration.

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14. Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Avnir et al (U.S. Patent No. 5,292,801, issued 8 March 1994) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) as applied to claims 1 and 26 above, and further in view of Croxson (U.S. Patent No. 5,108,891, issued 28 April 1992).

It is noted that while claim 27 has been rejected under 35 U.S.C 103(a) as described above in Section 12, the claim is also obvious using the interpretation outlined below.

Regarding claims 27 and 29, the biochip of claims 1 and 26 is discussed above in Section 12.

Kim et al teach the immobilized biomaterial IgG (page 333, column 1), which is a protein in the form of an antibody. In addition, Avnir et al also teach the biochip has anti-IL-2r, which is a protein in the form of an antibody that is an antigen to the antibody IL-2R, immobilized in the spots (column 10, lines 10-50). However, neither Kim et al, Avnir et al, nor Simon et al specifically teach the protein is the antibody HIV p24 (i.e., claims 27 and 29).

However, Croxson teaches the binding of molecules to protein HIV p24 (Abstract), wherein HIV p24 has the added advantage of being an indicator of the progression of HIV to AIDS (column 1, lines 40-67). Thus, Croxson teaches the known technique of binding molecules to HIV p24.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al in view of Avnir et al and Simon et al so that the immobilized protein biomaterial on the biochip is the HIV p24 protein of Croxson to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of allowing the assays performed with the biochip to indicate the progression of HIV to AIDS as explicitly taught by Croxson (column 1, lines 40-67). In addition, it would have been obvious to the ordinary artisan that the known technique of using the HIV p24 of Croxson could have been used as the biomaterial in the biochip of Kim et al in view of Avnir et al and Simon et al with predictable results because the HIV p24 of Croxson predictably results in a substrate useful for evaluation of the HIV progression in a patient.

15. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Avnir et al (U.S. Patent No. 5,292,801, issued 8 March 1994) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) as applied to claims 1 and 26 above, and further in view of Maracas et al (U.S. Patent No. 5,725,788, issue 10 March 1998).

Regarding claim 31, the biochip of claim 1 is discussed above in Section 12.

Kim et al teach the spots are formed via patterning using a stamp (Figure 1); however, neither Kim et al, Avnir et al, nor Simon et al specifically teach a spot diameter of about 100-500 microns.

However, Maracas et al teach biochips in the form of arrays of monolayer features (i.e., spots; Abstract), wherein the array is produced using a polydimethylsiloxane (i.e., PDMS) stamp producing circular spots of 0.1-1000 microns (Figure 1 and column 3, lines 35-55), which encompasses the claimed range of 100-500 microns. Maracas et al also teach the stamp has the added advantage of producing patterns quickly, easily, and reproducibly with low cost and low maintenance (column 1, lines 40-50). Thus, Maracas et al teach the known technique of producing spots having diameters in the range of 100-500 microns.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip comprising gel spots created with a PDMS stamp as taught by Kim et al in view of Avnir et al and Simon et al by using the PDMS stamp producing the 100-500 micron diameter gel spots as taught by Maracas et al to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of using a stamp that produces patterns quickly, easily, and reproducibly with low cost and low maintenance as explicitly taught by Maracas et al (column 1, lines 40-50). In addition, it would have been obvious to the ordinary artisan that the known technique of making the spot diameters of Maracas et al could have

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been used to form the chip substrate of Kim et al in view of Avnir et al and Simon et al with predictable results because the known technique of making the spot diameters of Maracas et al predictably results in a spot sizes useful for arrays

### ***Response to Arguments***

16. Applicant's arguments (filed 12 May 2009) with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

### ***Conclusion***

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Robert T. Crow  
Examiner  
Art Unit 1634

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Examiner, Art Unit 1634